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|-------------------------------|------------------------|---------------------|--|
| <b>Notice of Allowability</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                               | 09/433,777             | HAYNES ET AL.       |  |
|                               | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                               | Anne Marie S. Wehbe    | 1633                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- 1. ☒ This communication is responsive to the amendment filed on 8/23/06.
- 2. ☒ The allowed claim(s) is/are 48-62 and 64-77.
- 3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  - 1. ☐ Certified copies of the priority documents have been received.
  - 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

- 4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- 5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached.
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
- 6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                      |
| 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9. <input type="checkbox"/> Other _____.   |

## **REASONS FOR ALLOWANCE**

Applicant's amendment and response received on 8/23/06 has been entered. Claims 1-47 and 63 are canceled. Claims 48-62, and 64-77 are currently pending in the instant application.

### ***Nucleotide and/or Amino Acid Sequences***

Applicant's submission of a new sequence listing in paper and computer readable form (CRF) is acknowledged. The applicant's amendment of the specification to insert the appropriate SEQ ID NOS is also acknowledged. This application is now in compliance with the requirements of 37 CFR 1.821 through 1.825.

### ***Claim Rejections - 35 USC § 112, 102, and 103***

The rejection of claims 48-77 under 35 U.S.C. 112, second paragraph, for indefiniteness, the rejection of claims 60-62, 65, and 69-73 under 35 U.S.C. 102 (e) as being anticipated by U.S. Patent No. 5,925,362, hereafter referred to as Spitler et al., and the rejection of claims 66-68 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,925,362, hereafter referred to as Spitler et al., in view of Fynan et al., Golding et al., and Sedegah et al., are all withdrawn in view of applicant's amendments to the claims. Regarding the art rejections, note that the withdrawal of the 102 and 103 rejections is based on the amendment to claim 60 which now recites that both the nucleic acid molecule and the adjuvant are coated onto core carrier particles.

### ***Allowable Subject Matter***

Claims 48-62, and 64-77 are considered free of the prior art of record and allowable.

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The following is an examiner's statement of reasons for allowance: the claims as amended are now limited to coated particles wherein both a nucleic acid molecule comprising a sequence encoding an antigen and a non-DNA adjuvant are coated onto core carrier particles, and methods of eliciting an immune response against an antigen in an individual comprising co-administering core carrier particles coated with a sequence encoding an antigen and a non-DNA adjuvant.

While Fynan et al. and Sedegah et al. teach particle mediated delivery of nucleic acids encoding an antigen, and Golding teaches the benefits of using various non-DNA adjuvants to enhance immune responses, none of Fynan et al., Sedegah et al. nor Golding teach coating core carrier particles, such as gold particles commonly used in particle mediated DNA delivery, with a non-DNA adjuvant; and Spitler, while teaching the administration of liposomes comprising non-DNA adjuvant and a nucleic acid encoding an antigen, does not provide motivation for coating a core carrier particle with the non-DNA adjuvant. As such, the claims as amended are free of the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology

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center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

**ANNE M. WEHBE' PH.D**  
**PRIMARY EXAMINER**

A handwritten signature in black ink, appearing to read 'Anne M. Wehbe', with a long horizontal line extending to the right.